## UNITED STATES PATENT AND TRADEMARK OFFICE



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

Paper No.

NELSON MULLINS RILEY & SCARBOROUGH LLP FLOOR 30, SUITE 3000

ONE POST OFFICE SQUARE
BOSTON MA 02109

MAILED

FEB 2 2 2011

OFFICE OF PETITIONS

In re Application of

Chiba et al. : DECISION

Application No. 10/657,910 : ON APPLICATION FOR

Filed: Setpember 9, 2003 : PATENT TERM ADJUSTMENT

:

Atty Docket No. EISN-018CPRCE: Title: MACROCYCLIC COMPOUNDS: USEFUL AS PHARMACEUTICALS:

This is in response to the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(b)," filed January 19, 2011. Applicants submit that the correct patent term adjustment to be indicated on the patent is at least five hundred and thirty-one (531) days, not zero (0) days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicants request this correction partly on the basis that the Office will take in excess of three years to issue this patent. In addition, Applicants contend that a single period of applicant delay was miscalculated.

To the extent that the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is **DISMISSED** as **PREMATURE**.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under

§ 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, Applicants are advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, Applicants must timely file an application for patent term adjustment prior to the payment of the issue fee.

To the extent that Applicants otherwise requests reconsideration of the patent term adjustment at the time of the mailing of the notice of allowance, the request is **DISMISSED**.

For example, if Applicants dispute both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then Applicants must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the § 1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

## 37 C.F.R. § 1.704(b) sets forth, in pertinent part:

"With respect to the grounds for adjustment set forth in §§ 1.702(a) through (e), and in particular the ground of adjustment set forth in § 1.702(b), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed."

A non-final Office action was mailed on January 26, 2005, and a response was received three months and 97 days later on August 1, 2005. As such, the Office assessed a reduction of 97 days pursuant to 37 C.F.R. § 1.704(b).

In the "STATEMENT UNDER 37 CFR § 1.705(b)(2)," that was submitted concurrently with this petition (page 4, section B), Applicants argue "a response to the Office action mailed on January 26, 2005 was sent to the Office on July 26, 2005, and not on August 26, 2005 as is indicated on the PAIR PTA sheet. Accordingly, Applicants thereby incurred a delay of 91 days." The undersigned has reviewed the response that was received on August 1, 2005, and it is noted that it contains a certificate of mailing dated July 26, 2005.

Applicants' argument has been considered, and has been deemed to be unpersuasive. Applicants' attention is directed to 37 C.F.R. § 1.703(f), which provides that "[t]he date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation" of patent term adjustment. See also, Comment 10, Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term; Final Rule, 65 Fed. Reg. 54366 (September 18, 2000). Accordingly, since the 37

<sup>&</sup>lt;sup>2</sup> The Office notes that July 26, 2005 is three months and 91 days after the mailing of the non-final Office action.

<sup>&</sup>lt;sup>3</sup> The Office is construing this to be a typographical error, as the PAIR PTA sheet which Applicants have included with this petition indicates that the response was received on August 1, 2005, and not August 26, 2005.

C.F.R. § 1.8 exception to 37 C.F.R. § 1.6(a) does not apply to patent term adjustment calculations, for the purposes of calculating patent term adjustment, the controlling date for a paper that is physically mailed via the First Cass Mail service of the USPS is the date on which the paper is received in the Office.

The Office acknowledges submission of the \$200.00 fee set forth in 37 C.F.R. § 1.18(e). No additional fees are required.

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 C.F.R. § 1.705(d) and must include payment of the required fee under 37 C.F.R. § 1.18(e).

Applicants are reminded that any delays by the Office pursuant to 37 C.F.R. §§ 1.702(a)(4) and 1.702(b) and any applicant delays under 37 C.F.R. § 1.704(c)(10) will be calculated at the time of the issuance of the patent and Applicants will be notified of the revised patent term adjustment to be indicated on the patent in the Issue Notification letter that is mailed to applicants approximately three weeks prior to issuance.

The Office of Data Management has been advised of this decision. This matter is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries regarding this decision should be directed to Senior Attorney Paul Shanoski at (571) 272-3225.

/Paul Shanoski/
Paul Shanoski
Senior Attorney
Office of Petitions